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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,247	07/12/2004	Detlev Neuland	01/090LTS	5234

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EXAMINER	
HELM, CARALYNNE E	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,247	NEULAND ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 5-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, and 5-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 10, 2010 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3 and 7-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The disclosure as filed does not name any particular component in the broad classes of drug, food, cosmetic, and other undesirable substances that are recited as contaminating components removed by the instantly claimed method. Claim 1 implicitly requires that the contaminant material be able to be converted into a vapor at

approximately 80ºC. One of ordinary skill in the art could not immediately envisage the scope of actual components that correspond to these contaminating materials. The vaporization/sublimation temperature is not known for every food, drug, and cosmetic. In addition, all foods, cosmetics and drugs cannot be vaporized at approximately 80ºC. For example, tetracycline hydrochloride is a drug component known for inclusion in films that have been previously cast onto carriers (see Suzuki et al. column 4 lines 34-44 and column 5 line 62-column 6 line 8; see below for citation). Tetracycline hydrochloride melts at 214ºC (see Bittner et al. Journal of Controlled Release 1999 59:23-32; abstract). While reduced pressure can yield a sublimation temperature that is below a compound's melting temperature at ambient pressure, applicants do not envision the application of reduced pressure as a necessary step in the claimed process. In the absence of such reduced pressure, tetracycline hydrochloride would not be vaporized at approximately 80ºC and would not fall within the boundary of the instant invention. Applicants are lacking a structure-function correlation between the broad classes of materials recited and those that would actually be suitable for the invention (e.g. all foods, drugs, and cosmetics vs. foods, drugs, and cosmetics that are vaporized or sublimed at ambient pressure and approximately 80ºC). Therefore the specification does not clearly disclose to the artisan of ordinary skill which contaminating materials are removed from a carrier as part of the method applicants considered to be their invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5 and 6 recite the limitation "or other undesired substances" in line 12. There is insufficient antecedent basis for this limitation in the claims.

Claim 5 recites "the drug, food, or cosmetic contaminated carrier material" in step d, but in steps di and dii, "the drug, food, or cosmetic or other undesired substances" are removed from the carrier. This implies that materials other than drug food and cosmetic contaminate the carrier, but no other materials are recited in the listing of contaminants. Similarly in claim 6, "active ingredients, adjuvants, flavors, or fragrances" are recited as components that penetrate the and contaminate the carrier; however later in steps di and dii "the contaminants or other undesired material" are removed from the carrier as those something more than the recited contaminants can be entrapped in the carrier. Therefore the metes and bounds of the method are not known since it is not clear what contaminating material the method removes.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of Graham v. John Deere Co. have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. (US Patent No. 4,569,837) in view of McGinity et al. (US PGPub No. 2001/0006677), Chavannes (US Patent No. 2,486,258), Goldsworthy et al.(previously cited), and Barth (US Patent No. 4,622,761).

Suzuki et al. teach an oral pharmaceutical film that includes a water-soluble polymer along with one or multiple medicinal agents and optionally a plasticizer,

colorant, and flavoring (see abstract, column 4 lines 8-68, and column 5 lines 6-9 and 24-38). These components are dissolved in a solvent, where water is envisioned, yielding a casting solution (interpreted as aqueous active-ingredient containing drug coating) (see column 5 lines 39-53). The solution is cast via an endless belt type film preparing apparatus or other known methods for preparing a film (see column 5 line 62-column 6 line 8 and column 6 lines 19-22). The solvent is removed by any method customarily adopted in film preparing apparatus and later cut into a desired shape (see column 6 lines 9-17). Suzuki et al. do not explicitly teach additional details of the endless belt type process.

McGinity et al. teach that oral pharmaceutical films were known to contain surface markings such as lettering and numerals for the sake of identification (see paragraphs 1, 51-52, and 59).

Chavannes teaches a method of preparing a solution cast film (see column 2 lines 31-39). The casting process prepares a film with a surface design by passing a carrier, as an endless belt or on a reel, over a roller containing the film-forming solution on its surface (see column 3 lines 21-34, column 4 lines 31-63; instant claims 5a and 6a). The carrier is envisioned as a metal or paper (see column 3 lines 23-34). The carrier, with the applied film, then passes through a drying oven (see figure 7 and column 6 lines 34-38; instant claims 5b and 6b). The film is then stripped (interpreted as peeled) from the carrier by a roller that winds the film onto a reel (see figure 7 and column 6 lines 52-56; instant claims 5c and 6c). The carrier then passes through a buffing brush that cleans the carrier so that it will be ready to begin the coating circuit again (see column 6 lines 57-61). Applicants teach that components of the coating will

penetrate into and contaminate the carrier material when cast onto a substrate and later wound onto a reel (see instant specification page 2 lines 4-8 and page 3 lines 1-7). Therefore such contamination must also occur in the process of Chavannes.

Goldsworthy et al. teach a process of casting a polymer composite onto the surface of a belt (see column 2 lines 25-28). The material is allowed to cure/dry and is then removed from the belt (see column 2 lines 39-42). Goldsworthy et al. then teach the cleaning of the belt mechanically, with heat (thermal treatment) or solvent before it is returned to the initial portion of the machine for use in the process again (e.g. continuous belt) (see column 2 lines 43-47; instant claims 5di and 6di). Since applicant has not defined how much residual contaminant corresponds to removal of "essentially all of the contaminants", any amount of cleaning generated by the cleaning processes taught by Goldsworthy et al. are interpreted as removing "essentially all of the contaminants". Although not explicitly taught by Goldsworthy et al, it is commonly known that any cleaning methodology requires the disposal of the waste material removed from the cleaned item. In the case of thermal cleaning, the waste material is, at least in part, in gaseous form.

Barth teaches subjecting sheets of material on a continuous belt to a thermal treatment in a drying oven where the gaseous material removed from the sheets do not escape to the atmosphere (column 1 lines 57-64). Heated gas is introduced into a chamber through which the sheets travel (interpreted as a thermal treatment) (see figure 1 and column 2 lines 49-53). This treatment liberates material such as solvent and medicine residue which are carried by the gas (see column 3 lines 49-50). This refuse gas is collected by a withdrawal line that is connected to a vacuum pump that

removes this gas from the drying chamber to avert its entry into the atmosphere (see column 5 lines 58-67). The vacuum controls the circulation of the air by guiding it out of the drying chamber (controlled air circulation) (see instant claims 5dii and 6dii). Barth goes on to teach that the gas collected by the withdrawal line is fed to an afterburner (see column 3 lines 51-54; instant claims 5dii and 6dii).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the coating method of Chavannes to prepare the medicinal films of Suzuki et al. due to the suggestion by Suzuki et al. to utilize an endless belt type film preparing apparatus for their film and that of McGinity et al. to include lettering on oral pharmaceutical films to aid in identification. Additionally, it also would have been obvious to modify this method based on the teachings of Goldsworthy et al. who provide mechanical, thermal, and solvent cleaning as functionally equivalent means of cleaning an endless belt utilized in a coating casting method. Therefore the artisan of ordinary skill would also have found it obvious to use thermal treatment to clean the carrier of Suzuki et al. in view of Chavannes and McGinity et al., instead of taught mechanical means as a simple substitution of one known equivalent element for another to obtain a predictable result. Both Chavannes and the instant specification teach that the carrier employed in this method would become contaminated with material form the coating solution and these contaminants would include medicinal agent, flavorings, solvent, colorants, and plasticizers (see instant claims 5d-5di and 6d-6di). Since Barth teaches an apparatus that provides a thermal treatment to a continuous belt of sheet material that removes material from its surface, it would also have been one of ordinary skill in the art at the time of the invention to utilize this apparatus as the source of thermal

treatment for the method of Suzuki et al. in view of Chavannes, McGinity et al., and Goldsworthy as a the use of a known technique to improve a similar product in the same way (e.g. removal of undesired components from sheets of product with heat). Therefore claims 5 and 6 are obvious over Suzuki et al. in view of Chavannes, McGinity et al., Goldsworthy et al., and Barth.

Claims 1, 3, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. in view of Chavannes, McGinity et al., Goldsworthy et al., and Barth as applied to claims 5 and 6 above, and further in view of Lerdkanchanaporn et al. (Thermochimica Acta 2000 357-358:71-78) and Lerdkanchanaporn et al. (Journal of Thermal Analysis 1887 49:879-886; henceforth Lerdkanchanaporn B).

Suzuki et al. in view of Chavannes, McGinity et al., Goldsworthy et al., and Barth make obvious the method of method for removing contaminating or undesired substances from a carrier material comprising: a) coating an active-ingredient-containing drug, food or cosmetic coating onto a neutralized carrier material [Applicants teach that neutralization occurs when a carrier is made to be essentially free of contaminants from a coating that was previously applied and removed (see instant specification page 4 lines 16-19). Therefore the cleaned carrier of Suzuki et al. in view of Chavannes, McGinity et al., Goldsworthy, and Barth that is fed back to the coating process is a neutralized carrier], substances within said coating penetrating into and thereby contaminating said carrier material with drug, food or cosmetic contaminants or other undesired substances, b) drying the coated carrier material to form an active-ingredient-containing or cosmetic film, c) peeling the dried active-ingredient- containing

film off the contaminated carrier material and d) subjecting the contaminated carrier material to a thermal treatment which comprises i) passing said contaminated carrier material through a thermal treatment zone at a temperature and during a period of time sufficient to remove essentially all of the drug, food or cosmetic contaminants or other undesired substances from the carrier material to form neutralized carrier material, and ii) feeding the removed contaminants or other undesired substances to a thermal after-burning using controlled air circulation, and e) providing the neutralized carrier material to said coating step. Within the highlighted teachings, this modified reference provides for a paper carrier on a reel (e.g. instant claims 1e and 3), the drying apparatus of Barth forms a tunnel through which the contaminated carrier would travel, therefore qualifying as a drying tunnel (see figure 1; instant claim 7), and the reuse of the carrier in the coating process after it has been cleaned (see instant claim 7). Additionally, since Suzuki et al. teach ibuprofen as a drug envisioned in their film, this modified reference also renders this decontamination method obvious when the coated film contains ibuprofen (see column 4 lines 33-36 and 56). The modified reference does not explicitly teach the temperature at which the cleaning thermal treatment occurs or the time over which the treatment is applied.

Lerdkanchanaporn et al. teach that ibuprofen evaporates at 75°C -77°C at atmospheric pressure (see page 71 column 1 paragraph 1).

Lerdkanchanaporn B teaches the coefficient of evaporation per unit area for ibuprofen at a variety of temperatures. A power law fit of this data allows extrapolation of the coefficient of evaporation per area at 77°C which corresponds to approximately

$4.22x10^{-5}$ mg/cm^{2}s [power law fit of data by examiner yields: (coefficient of evaporation per area) = 10^{-63} x (temperature in Kelvin)$^{23.044}$].

Suzuki et al. in view of Chavannes, McGinity et al., Goldsworthy et al., and Barth clearly envision the contamination of the carrier with material from the film that has been removed. Both one of ordinary skill in the art and the instant inventors would expect that traces of any of the components in the coating would remain on the carrier as contaminants, and these include the drug. Since Lerdkanchanaporn et al. teach that ibuprofen evaporates at 77ºC, it would have been obvious to one of ordinary skill in the art to apply the taught thermal treatment that cleans the carrier at this temperature to remove residual drug. The temperature 77ºC can be interpreted as "approximately 80 ºC" since applicants have not provided a limiting definition of the term "about" that defines it otherwise. While Suzuki et al. in view of Chavannes, McGinity et al., Goldsworthy et al., Barth, and Lerdkanchanaporn et al. do not explicitly teach the time for the removal of essentially all the undesired substances, the approximate rate of ibuprofen evaporation per area (e.g. coefficient of evaporation) was known based upon the teachings of Lerdkanchanaporn B. One of ordinary skill in the art would have been aware of the dimensions of the carrier and film composition as well as the corresponding amount of carrier contamination. As a result effective variable, it would have been obvious to the artisan of ordinary skill to optimize the thermal treatment cleaning time in light of this data as a matter of routine experimentation. Thus claims 1, 3, and 7 are obvious over Suzuki et al. in view of Chavannes, McGinity et al., Goldsworthy et al., Barth, Lerdkanchanaporn et al. and Lerdkanchanaporn B.

Claims 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. in view of McGinity et al., Chavannes, Goldsworthy et al.(previously cited), Dieudonne et al. (US Patent No. 4,978,836), Wimberger et al. (previously cited), Lerdkanchanaporn et al. and Lerdkanchanaporn B.

Suzuki et al. teach an oral pharmaceutical film that includes a water-soluble polymer along with one or multiple medicinal agents and optionally a plasticizer, colorant, and flavoring (see abstract, column 4 lines 8-68, and column 5 lines 6-9 and 24-38). Ibuprofen is an envisioned medicinal agent (see column 4 lines 33-36 and 56). These components are dissolved in a solvent, where water is envisioned, yielding a casting solution (interpreted as aqueous active-ingredient containing drug coating) (see column 5 lines 39-53). The solution is cast via an endless belt type film preparing apparatus or other known methods for preparing a film (see column 5 line 62-column 6 line 8 and column 6 lines 19-22). The solvent is removed by any method customarily adopted in film preparing apparatus and later cut into a desired shape (see column 6 lines 9-17). Suzuki et al. do not explicitly teach additional details of the endless belt type process.

McGinity et al. teach that oral pharmaceutical films were known to contain surface markings such as lettering and numerals for the sake of identification (see paragraphs 1, 51-52, and 59).

Chavannes teaches a method of preparing a solution cast film (see column 2 lines 31-39). The casting process prepares a film with a surface design by passing a carrier, as an endless belt or on a reel, over a roller containing the film-forming solution on its surface (see column 3 lines 21-34, column 4 lines 31-63; instant claims 1a). The

carrier is envisioned as a metal or paper (see column 3 lines 23-34). The carrier, with the applied film, then passes through a drying oven (see figure 7 and column 6 lines 34-38; instant claims 1b). The film is then stripped (interpreted as peeled) from the carrier by a roller that winds the film onto a reel (see figure 7 and column 6 lines 52-56; instant claims 1c). The carrier then passes through a buffing brush that cleans the carrier so that it will be ready to begin the coating circuit again (see column 6 lines 57-61). Applicants teach that components of the coating will penetrate into and contaminate the carrier material when cast onto a substrate and later wound onto a reel (see instant specification page 2 lines 4-8 and page 3 lines 1-7). Therefore such contamination must also occur in the process of Chavannes.

Goldsworthy et al. teach a process of casting a polymer composite onto the surface of a belt (see column 2 lines 25-28). The material is allowed to cure/dry and is then removed from the belt (see column 2 lines 39-42). Goldsworthy et al. then teach the cleaning of the belt mechanically, with heat (thermal treatment) or solvent before it is returned to the initial portion of the machine for use in the process again (e.g. continuous belt) (see column 2 lines 43-47; instant claims 1di). Since applicant has not defined how much residual contaminant corresponds to removal of "essentially all of the contaminants", any amount of cleaning generated by the cleaning processes taught by Goldsworthy et al. are interpreted as removing "essentially all of the contaminants". Although not explicitly taught by Goldsworthy et al, it is commonly known that any cleaning methodology requires the disposal of the waste material removed from the cleaned item. In the case of thermal cleaning, the waste material is, at least in part, in gaseous form.

Dieudonne et al. teach an infrared radiator in a continuous oven as a means of applying a thermal treatment to thin plate-like components (see abstract and column 1 lines 4-8)

Wimberger et al. teach a process where a paper web (carrier) is passed through a thermal treatment zone such that a surface contaminant (solvent) is removed via a thermal treatment and fed to an afterburner via a fan (controlled air circulation) (see column 1 lines 50-59, column 2 lines 66-68; instant claims 1 and 3).

Lerdkanchanaporn et al. teach that ibuprofen evaporates at 75ºC -77ºC at atmospheric pressure (see page 71 column 1 paragraph 1).

Lerdkanchanaporn B teaches the coefficient of evaporation per unit area for ibuprofen a variety of temperatures. A power law fit of this data allows extrapolation of the coefficient of evaporation per area at 77ºC which corresponds to approximately 4.22×10^{-5} mg/cm^{2}s [power law fit of data by examiner yields: (coefficient of evaporation per area) = 10^{-63} x (temperature in Kelvin)$^{23.044}$].

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the coating method of Chavannes to prepare the medicinal films of Suzuki et al. due to the suggestion by Suzuki et al. to utilize an endless belt type film preparing apparatus for their film and that of McGinity et al. to include lettering on oral pharmaceutical films to aid in identification. Additionally, it also would have been obvious to modify this method based on the teachings of Goldsworthy et al. who provide mechanical, thermal, and solvent cleaning as functionally equivalent means of cleaning an endless belt utilized in a coating casting method. Therefore the artisan of ordinary skill would also have found it obvious to use thermal treatment to clean the carrier of

Suzuki et al. in view of Chavannes and McGinity et al., instead of taught mechanical means as a simple substitution of one known equivalent element for another to obtain a predictable result. Both Chavannes and the instant specification teach that the carrier employed in this method would become contaminated with material form the coating solution and these contaminants would include medicinal agent, flavorings, solvent, colorants, and plasticizers (see instant claims 1d-1di). Since Dieudonne et al. teaches an apparatus that provides a thermal treatment to a continuous belt of plate-like material, it would also have been one of ordinary skill in the art at the time of the invention to utilize this apparatus as the source of thermal treatment for the method of Suzuki et al. in view of Chavannes, McGinity et al., and Goldsworthy as a simple substitution of one known equivalent element for another (e.g. general thermal treatment device for infrared thermal treatment device). This thermal cleaning treatment would necessarily liberate gaseous waste, therefore it also would have been obvious to feed this material to an afterburner as taught by Wimberger et al. as the application of a known technique to a similar method ready for improvement to yield a predictable result.

Suzuki et al. in view of Chavannes, McGinity et al., Goldsworthy et al., Dieudonne et al., and Wimberger et al. clearly envision the contamination of the carrier with material from the film that has been removed as well as ibuprofen as a component of the film. Both one of ordinary skill in the art and the instant inventors would expect that traces of any of the components in the coating would remain on the carrier as contaminants, and these include the drug. Since Lerdkanchanaporn et al. teach that ibuprofen evaporates at 77°C, it would have been obvious to one of ordinary skill in the art to apply the taught thermal treatment that cleans the carrier at this temperature to

remove residual drug. The temperature 77ºC can be interpreted as "approximately 80 ºC" since applicants have not provided a limiting definition of the term "about" that defines it otherwise. Suzuki et al. in view of Chavannes, McGinity et al., Goldsworthy et al., Dieudonne et al., and Wimberger et al. do not explicitly teach the time for the removal of essentially all of the undesired substances, the approximate rate of ibuprofen evaporation per area (coefficient of evaporation) was known based upon the teachings of Lerdkanchanaporn B. One of ordinary skill in the art would have been aware of the dimensions of the carrier and film composition as well as the corresponding amount of carrier contamination. As a result effective variable, it would have been obvious to the artisan of ordinary skill to optimize the thermal treatment cleaning time in light of this data as a matter of routine experimentation. Thus claims 1 and 8 are obvious over Suzuki et al. in view of Chavannes, McGinity et al., Goldsworthy et al., Dieudonne et al., Wimberger et al., Lerdkanchanaporn et al. and Lerdkanchanaporn B.

Response to Arguments

Applicants' arguments submitted February 10, 2010, have been fully considered but are moot in light of the new grounds of rejection.

It is worthy of note that applicants provided a piecemeal collection of arguments, highlighting that each of the cited references did not teach the invention in its entirety on its own as well as aspects in each reference that were unrelated to the instantly claimed invention. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references.

Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

All previous rejections are hereby withdrawn. The rejections detailed above are either are newly applied and constitute the complete set presently being applied to the instant application.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Friday 9-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Juliet C Switzer/
Primary Examiner, Art Unit 1634